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Attorney Docket No. 31140C

REMARKS

The Examiner issued new rejections of the claims under 35 U.S.C. §112.

The Examiner rejected claims 35-51 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner maintained that the term "less than frequently" is new matter. The Examiner stated that the closest recitation is shown at page 16, lines 24-25 which relates to a frequency of monthly or less than monthly. Applicants respectfully traverse this rejection. Applicants note that at page 16, lines 21-22, the specification states that the invention "can include daily or other periodic administration of Vitamin D compounds." The recitation of a periodic administration other than daily clearly conveys to a person skilled in the art that one aspect of the invention includes administering the Vitamin D compound on a basis of less frequent than daily (the manner where the medicament is administered on a most frequent basis).

The Examiner also rejected claims 52-61 and 71-90 under §35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the specification recites periodic administration, but not periodic basis as claimed. Applicants believe that the specification fully supports the phrase periodic basis. However, in order to moot the issue, Applicants respectfully amend independent claims 52, 71 and 82 to use the language pointed out by the Examiner (independent claim 61 does not recite the "periodic basis" language). Specifically, claims 52, 71 and 82 have been amended to recite "periodically administering," and that the administration is not daily. Once again, at page 16, lines 21-22, the specification clearly states that the administration can be daily or some other periodic administration.

The Examiner has also rejected claims 31-36, 43-45, 52-54, 61-64, 71-74 and 82-84 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner stated that the claims do not state the lower dosages required to effect increased apoptosis. With respect to apoptosis, applicants state that there are ways that are well known in the art for measuring apoptosis and that this rejection should not be maintained. The Examiner has also questioned the dosage required without inducing hypercalcemic side effect. Applicants state that it is well known in the art how to test patients for hypercalcemic side effect. These tests are routinely conducted. Applicants can provide a declaration of a person of ordinary skill in the art if the Examiner believes this is necessary. However, Applicants respectfully submit that this should not be necessary since it is well known in the art.

The Examiner has maintained the prior rejection under 35 U.S.C. §112, second paragraph, as being indefinite in connection with administration of a Vitamin D compound that is not on a daily basis. The Examiner states that this administration can be once every other day, once a week, etc. Applicants respectfully transverse the rejection. The Examiner notes that a medication can be administration four times a day. In fact, such administration four times a day each day would be on a daily basis. Applicants' claim limitation is quite precise. It states simply that the administration is less frequent than daily. A medication administrated four times every day is a daily administration. The claim does not state only that the patient should take the medication less frequently. Rather, the claim states that it is administered on a less frequent then daily basis. That means that it could be done for example, every other day, once a week, once every other month, once a year, etc. However, it would exclude administration on a daily basis.

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Applicants once again request the opportunity to conduct an interview with the Examiner to discuss these issues. Applicants request allowance of the claims.

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Respectfully submitted,

Raymond N. Nimrod
Reg. No. 31,987
Jenner & Block
330 N. Wabash
One IBM Plaza
Chicago, Illinois 60611
Tel (312) 923-8306